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SL

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 087835,482      | 04/08/97    | ROBIN                | A 002               |

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HM12/0126

EXAMINER

SEIDLECK, B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1615     | 11           |

DATE MAILED: 01/26/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

|                              |                                      |                               |
|------------------------------|--------------------------------------|-------------------------------|
| <b>Office Action Summary</b> | Application No.<br><b>08/835,482</b> | Applicant(s)<br><b>Rubin</b>  |
|                              | Examiner<br><b>Brian K. Seidleck</b> | Group Art Unit<br><b>1615</b> |

Responsive to communication(s) filed on Dec 1, 1998

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1, 2, 5, 8, and 11-16 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1, 2, 5, 8, and 11-16 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

***Papers Received***

1. Receipt is acknowledged of applicant's Amendment and Response filed on 12/1/98.

***Response to Arguments***

2. Applicant's arguments filed 12/1/98 have been fully considered but they are not persuasive. Examiner maintains his original rejections and thus claims 1-2, 5, 8, and 11-16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Dempski et al (U.S. Pat. No. 4,900,755, collectively "Dempski") and Conte et al (U.S. Pat. No. 5,738,874, collectively "Conte").

The applicant claim the present invention has solved the problems of the prior art by providing an effective formulation having both immediate and sustained release properties to provide immediate and long lasting therapeutic action of carbidopa-levodopa to treat Parkinson's disease. However, the examiner again notes that the present specification contains no data to demonstrate this claimed novelty for the treatment of Parkinson's. Thus, the applicant has not provided sufficient evidence to demonstrate an improvement over the prior art of record. It is well known in the art that formulations containing both an immediate and sustained release profile allow for the active(s) to enter the bloodstream quickly and to maintain effective concentrations over an extended period of time.

As stated in the previous office action, the combination of levodopa and carbidopa in a sustained release formulation is well known in the art. The art recognizes the importance of

treating Parkinson's disease with a dosage form which prevents the emergence of "wearing-off" and "on-off" phenomena. Further the prior art teaches formulation comprising multiple release layers to provide for immediate and sustained release of actives, including levodopa and carbidopa. Specifically, Conte teaches a pharmaceutical tablet capable of releasing one or more drugs at different release rates in either a two layered or three layered formulation. See abstract and drawings. The first layer contains one or more drugs with an immediate release profile and a second layer containing one or more drugs with a sustained release profile. Id. Conte teaches both levodopa and carbidopa. See Col. 18, claim 6. An optional polymeric barrier can be placed between the first and second layers. See abstract. Conte teaches combination therapy with both levodopa and carbidopa in a formulation with multiple release profiles. See Cols. 2-3.

### *Conclusion*

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Brian K. Seidleck** whose telephone number is **(703) 305-4448**. The examiner can normally be reached **Monday through Friday from 6:30am to 3:00pm**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K. Page**, can be reached on **(703) 308-2927**. The official fax numbers for Technology Center 1600 are **(703) 305-3592** and **(703) 308-4556**. The unofficial fax number is **(703) 308-7924**.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. § 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[thurman.page@uspto.gov]**.

**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of confidentiality requirements of U.S.C. § 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.**

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Rubin

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center receptionist whose telephone number is (703) 308-1235 or (703) 308-1234.

Brian K. Seidleck  
Patent Examiner  
January 21, 1999

*T. K. Page*  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
ART UNIT 152 1615